

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: The University of Georgia Research Foundation, Inc.

International Application No. PCT/US03/22011

Filed: July 10, 2003

For: MYCOPLASMA GALLISEPTICUM FORMULATION

Commissioner of Patents and Trademarks Box PCT Washington, DC 20231

Sir:

RESPONSE TO WRITTEN OPINION

The written opinion dated 15 November 2004 indicated that all of the claims were anticipated by or obvious in view of U.S. Patent No. 5,766,594 to Kodama et al. (Kodama 1), U.S. Patent No. 5,621,076 to Kodama et al. (Kodama 2), U.S. Patent No. 5,489,430 to Saito et al., U.S. Patent No. 5,004,607 to Ragland et al., and EP 0 603 406 A1 to Nippon Zeon Co., LTD. This finding appears to be in error, and reconsideration in light of the following remarks is respectfully requested.

The present invention is directed towards a *Mycoplasma Gallisepticum* (MG) vaccine formed from an MG bacterial strain having a RAPD pattern substantially corresponding to at least one of the band patterns of K5054 and a carrier. Specifically, the present invention provides a vaccine using attenuated whole organisms that is particularly suited for use in turkeys whereas earlier vaccines using other strains or mere fragments of MG were not as successful in turkeys

The cited references, however, do not suggest or teach the present invention. None of the references teach the use of a whole, live organism for use as a vaccine. Both Kodama 1 and Kodama 2 cite a DNA fragment from MG that encodes a polypeptide that is used for a vaccine.

70609.doc

The polypeptides elicit an immune response from a chicken. The present invention, however, claims a vaccine made from a unique, attenuated, whole living organism. Kodama 1 and Kodama 2 claim a component vaccine, in that it consists of an isolated part of an MG organism (Kodama 1 column 3, line 41).

The Saito patent teaches a single polypeptide for use in a vaccine against MG. Saito uses an isolated component of a whole organism rather than an attenuated, whole living organism as in the present invention. (Column 1, Lines 42-43 and Column 2, Lines 16-18)

Ragland teaches a method for immunizing poultry using dead MG organisms and a two part inoculation method. The first inoculation is intracoelomic, and the second could be delivered to a variety of different sites. The present invention does not teach intracoelomic inoculation using dead organisms. (Column 1, Lines 12-16)

Similarly, Nippon Zeon also teaches a component vaccine using proteins that react with antisera against MG. (Page 3, Lines 18-19)

The cited references actually teach away from the present invention. Kodama 1 and Kodama 2 both say "using attenuated *Mycoplasma* might rather cause opportunistic infections." (Kodama 1 Column 1, lines 48-49 and Kodama 2 Column 1, Lines 46-47) Ragland says "the attenuated strain does cause mild, transitory disease. Furthermore, the U.S. Department of Agriculture has been reluctant to approve such an attenuated vaccine because of its potential prolonged existence in the environment and the potential to revert to a virulent strain." (Column 1, Lines 45-51) As such, the present invention is not obvious or anticipated by the cited references since there was a widely held belief in the art that the use of a whole, living organism would cause disease rather than vaccination against MG.

Each of the present claims is patentably distinguishable over the cited references. Thus, Applicant respectfully requests that the International Preliminary Search Report reflect the patentability of the claimed invention.

Respectfully submitted,

Howard A. MacCord, Jr. Registration No. 28,639

P.O. Box 2974

Greensboro, NC 27402 Phone: (336) 273-4422

Date: <u>December 14, 2004</u> Reference No.: 7700-002-01

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS DOCUMENT IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL, IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, ON <u>December 14, 2004</u> (Date of Deposit)

> Christian E. Carter-Seyboth Name of Depositor

Mistian C. Cart - Sypoth

December 14, 2004
Date of Signature